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October 21, 1999

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Petition For Reconsideration
Docket No. 99P-1516

Dear Sir or Madam:

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. 99P-1516.

A. Decision Involved

The Food and Drug Administration (FDA) through an October 6, 1999 letter from the Director of the Center for Devices and Radiological Health (CDRH) decided to deny the above referenced petition. Irrespective of the fact that this decision was expressed by the CDRH Director rather than the Commissioner as described in 21 C.F.R. § 10.30, it is the "wish" of the petitioner that the Commissioner of the Food and Drug Administration (FDA) reconsider the apparent decision of the FDA.

B. Action Requested

The petitioner requests that the Commissioner undertake to identify "Reprocessed Single Use Devices" as Banned Devices in accordance with Section 516 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 360f and the "Banned Devices" regulation appearing in the Code of Federal Regulations (C.F.R.) at 21 C.F.R. Part 895. The objective of this petition was to seek the prompt banning

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PRC 1

of reprocessed single use devices, but it invoked on page 8 of the petition the regulations appearing in 21 C.F.R. Part 895 recognizing that ultimate banning of these reprocessed single use devices would necessitate application of the procedures appearing in this regulation.

The petitioner recognizes the flexibility that the Commissioner possesses under 21 C.F.R. § 10.30(e) to "grant or deny such a petition, in whole or in part, and . . . grant such other relief or take other action as the petition warrants" as well as to provide a tentative response. The petitioner believes action by the Commissioner, other than denial, represent available and appropriate options for the FDA to assure that adulterated and/or misbranded devices do not remain in interstate commerce.

C. Statement of grounds

The factual and legal grounds upon which the petition relies are described in the petition itself. Moreover, the applicable FDA regulation states that "A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made." 21 C.F.R. § 10.33(e). The petitioner recognizes that administrative records may exist which are not in the public file for Docket No. 99-1516. Therefore, it cannot address issues which may be part of the administrative record; because, such administrative record documents in the possession of the FDA have not been disclosed.

The petitioner can and does comment on the two-page document conveyed by the FDA as grounds for denial. Both the denial letter and the petitioner's response appear as Exhibit A. Quite simply, the MDMA believes that the October 6, 1999 letter makes quite clear that relevant information or views were neither previously nor adequately considered.

In reference to the documents appearing in Exhibit A, it should be obvious to any reader that the brief two paragraph "reasoning" for denial bears no resemblance to the substance of the twenty (20) pages of the petition. As a matter of fact, the one paragraph cites a "clear evidence" standard or justification for denial though such a threshold is not mandated either under the FDCA or the Banned Devices regulation. The petition itself provides a clear description of the FDCA criteria, the legislative references providing meaning to these criteria; and references, including documented evidence (e.g., see p. 15 of petition referencing FDA Docket No. 97N-0477), in support of the criteria identified in the FDCA.

The petitioner recognizes that promulgation of a regulation requires notice and comment rulemaking. It also recognizes that the FDA can undertake to gather evidence, including consultation with a statutory advisory panel, prior to proceeding with publication of a proposed regulation. Publication of a proposal will provide the public with the opportunity to comment and may result in the production of evidence to demonstrate harm and/or the level of public deception. The possibility that the FDA may not make a proposed regulation immediately effective was not intended by the petitioner as a reason to abandon the process of identifying reprocessed single use devices as banned devices. It was for this reason, in part, that the petition on page 8 referenced the application of the Banned Device Regulations appearing in 21 C.F.R. Part 895. The petitioner believed then and restates now that the criteria for application of 21 C.F.R Part 895 are present and have been expressed in the petition.

The four sentence paragraph relied on by the FDA in the October 6, 1999 letter to support its reasoning improperly relies on a non-existent "clear evidence" criterion. Moreover, the failure of the FDA to provide an analysis of its review of the petition, and the absence of any explanation or identification of the "adverse event reports" are a pathetic effort to ignore the substance of the petition and represent arbitrary, capricious, and abuse of discretionary authority conduct by the FDA.

With regard to the five sentence paragraph in the October 6, 1999 letter referencing the concept of deception, the FDA attributes a suggestion to the petition for which there simply is no basis in fact or the text of the petition. The petition addresses the criteria applicable to the concept of substantial deception. It properly cites the legislative reference that no " . . .actual proof of deception of or injury to an individual [is] required." As a matter of fact, the previously cited Banned Devices regulation discusses criteria for determining whether a device is deceptive. In part, the regulation at 21 C.F.R. § 895.21(a)(2) states:

> The Commissioner is not required to determine that there was an intent on the part of the manufacturer, distributor, importer, or any other responsible person (s) to mislead or otherwise harm users of the device or that there exists any actual proof of deception of, or injury to, an individual. (Emphasis Added).

Yet, the FDA, in defiance of its own regulation, which has been in effect for twenty years, denies the petition on the basis that there is "no evidence" of danger to

health. Irrespective of whether "evidence" is a synonym for "proof", the fact in law is that "actual proof" of "deception" is "not required" to initiate a banning procedure.

The justification by the FDA, as distinct from its improper characterization of the petition, represents a careless effort to deny a carefully worded and substantive petition relying on both fact and law. The public is entitled to better performance by the FDA. The petitioner believes that it has met the burden to justify initiation of a proceeding to identify reprocessed single use devices as banned devices. It reiterates this plea to the Commissioner herself in this petition for reconsideration.

The petitioner believes that if the Commissioner will display careful consideration and a thorough analysis of this petition that she will identify an option other than the inadequate missive conveyed on October 6, 1999. Moreover, conscientious review by the Commissioner will confirm that:

1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

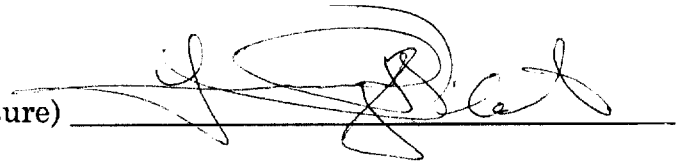
2) The petitioner's position is not frivolous and is being pursued in good faith.

3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

4) Reconsideration is not outweighed by public health or other public interest – to the contrary, public health and public interest justify the need for the FDA to prevent unequivocal adulteration and misbranding of single use devices rather than act after the death or serious injury has occurred.

As part of this request to the Commissioner for reconsideration, the petitioner further requests that the Commissioner direct the recusal of individuals in the CDRH or elsewhere in the FDA who were involved in any way with the October 6,1999 letter unless such involvement is open to the public and all records of such prior involvement are disclosed through filings in the docket for 99P-1516.

In summary, the MDMA appreciates this opportunity for reconsideration and welcomes the possibility of any reasonable initiative by the Commissioner to address an issue of major importance to the public health responsibility of the FDA.

(Signature) 

by Larry R. Pilot, Esq.
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Public Health Service

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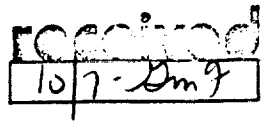

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Re: Docket No.. 99P-1516/CP 1

Dear Mr. Pilot:

This letter is in response to your citizen petition on behalf of the Medical Device Manufacturers Association (MDMA), dated May 20, 1999, requesting that the Food and Drug Administration (FDA) issue a proposed regulation identifying reprocessed single use devices as banned devices and that such proposed regulation be made effective upon its publication in the Federal Register. As stated, the petition applies to practitioners, institutions, and reprocessors. Thank you for the detailed petition and the issues you raised. We regret the delay in responding.

The petition requests that FDA issue a proposed regulation to ban the practice of reprocessing single use devices and to make the ban effective on the date of publication of the proposed regulation in the Federal Register. The stated grounds for the petition included a statement that the "complexity of these devices for their intended use severely constricts any possibility of cleaning and sterilizing the device in order to restore it to its original unused condition." Your letter also stated that manufacturers are required to obtain PMA approval or 510(k) clearance for their devices and that "FDA required labeling" for such devices must state that they are for single use and are not to be reused. You stated that this requirement must be met in the absence of information provided to FDA demonstrating that reprocessing will not adversely affect product safety or effectiveness.

FDA has carefully reviewed your petition to ban the reprocessing of single use devices, and we are denying it. The Agency does not believe that banning is the appropriate action to address the many and varied issues tied to this practice. Our reasoning follows.

There is no clear evidence that reprocessing presents "an unreasonable and substantial risk of illness or injury," which is one of the criteria for banning a medical device. FDA

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David W. Feigal, Jr., M.D., M.P.H
Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: Docket No. 99P-1516

Dear Dr. Feigal:

This acknowledges receipt of your letter denying the above-referenced petition to identify reprocessed single use devices as banned devices. The Medical Device Manufacturers Association (MDMA) is disappointed with your position, but the MDMA maintains that the Director of the Center for Devices and Radiological Health (CDRH) is not authorized to deny the petition. By regulation, this function is performed by the Commissioner, and there has not been a delegation of authority from the Commissioner to the CDRH Director.[1]

The MDMA is genuinely concerned about the effect on public health created by Food and Drug Administration (FDA) failure to enforce applicable laws and regulations. Moreover, the MDMA is surprised by the two-paragraph reasoning of the Agency and mischaracterization of the content of the petition itself.

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[1] Food and Drug Administration regulations describing "Delegations of Authority and Organization" restrict the authority of the Director and Deputy Director of CDRH to issuance of a tentative response only. See 21 C.F.R.§ 5.31 (e) (5).

The FDA acknowledges receipt of adverse events, but it provides no explanation or reference to the number, type of device, method of analysis, type of injury, source, or other information to support the relevance of any finding by the FDA. This cavalier dismissal relying on FDA inability "to find clear evidence of adverse patient outcomes" is not consistent with either the statutory language, legislative history, or FDA's own regulation appearing in 21 C.F.R. Part 895.

The MDMA petition clearly describes the statutory language and legislative intent. Although the FDA has discretionary authority with regard to application of its responsibility, the Federal, Food, Drug, and Cosmetic Act (FDCA) does not require "clear evidence of adverse patient outcomes" to support initiation of the banning procedure. The content of your letter and FDA performance to date suggest that action against an adulterated and misbranded device will not be commenced by the FDA unless there is "clear evidence" of death or serious injury. For the FDA to convey this impression and tolerate continuous violation of the FDCA creates an image of the FDA that is contrary to the preventative and remedial purpose of the FDCA.

With regard to the paragraph describing the reasoning of the FDA on the issue of substantial deception, nowhere does the MDMA in its petition suggest "it would be difficult to establish whether deception with respect to reprocessed devices has occurred and who was the target of that deception." Quite the contrary, this issue can be explored simply through a survey of those who are about to be subjected to the use of a reprocessed device or who have been subjected to such use without their knowledge. Irrespective of whether deception is established, the petition itself quotes the legislative reference "Nor is actual proof of deception of or injury to an individual required." Additionally, during a recent appearance by an American Hospital Association (AHA) representative on the television program "Good Morning America," when the AHA representative was asked about patient knowledge relating to a reused object, he expressed the position of the AHA that "there should be informed consent."

Because neither the FDCA nor the Banned Devices regulation mandate that "evidence" is required to support "danger to individual health," it is facile for the FDA to conclude in support of the denial of the petition that "this burden has not been met." As to whether "banning does not seem to be an appropriate response" for what is a public health issue directly related to the adulteration and misbranding of devices, initiation of the process as described in 21 C.F.R. Part 895 is an appropriate procedure to apply. For example, before initiating a proceeding,

the Commissioner may consult with an advisory panel during a regular or specially scheduled meeting. This approach would provide the opportunity for public participation prior to commencement of rule making. Application of the procedures for banning a device as described in 21 C.F.R. § 895.21 is consistent with the objective of the MDMA petition.

Finally, notwithstanding the fact that only the Commissioner is authorized to deny the above referenced petition, the MDMA has no desire to encounter further delays which would affect ripeness for adjudication if litigation becomes necessary. Consequently, it is filing an administrative reconsideration of action pursuant to 21 C.F.R. § 10.33. As part of this request for reconsideration and in response to your letter, the MDMA respectfully requests preservation of all present and future documents in the possession of the FDA in the form of telephone conversations, meetings, conferences, memoranda, correspondence, e-mails, computer records, etc. which relate to the subject matter associated with this petition. This will assure availability of documents for subsequent disclosure either under the Freedom of Information Act (FOIA) and/or through possible legal action in the courts.

On behalf of the MDMA, I appreciate your interest in providing a prompt response and welcome the opportunity for future, and hopefully constructive, dialogue on this subject.

Cordially,

Larry R. Pilot

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cc: S. Northrup
Documents Management Branch